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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 10/001,765 | 10/31/2001 | Donald T. Shannon | VAS-5041CIP1 | 5826 |
| 7590 | 10/29/2003 | | EXAMINER | |
| Edwards Lifesciences LLC Law Dept. One Edwards Way Irvine, CA 92614 | | | PELLEGRINO, BRIAN E | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3738 | |
| | | | DATE MAILED: 10/29/2003 | |
| | | | 6 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) |
|------------------------------|--------------------------------|----------------------------|
| | 10/001,765 | SHANNON ET AL. <i>(CR)</i> |
| | Examiner Brian E Pellegrino | Art Unit 3738 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 02 September 2003 .

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 114-137 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 114-137 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____ .
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other: _____

DETAILED ACTION

Response to Amendment

Applicant's request for consideration of the amendment to the claims and entry prior to examination is acceptable and, therefore, the restriction of the prior office action is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 114-117,121-129,133-137 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banas et al. (5749880) in view of Frantzen (6042606). Banas et al. disclose an expandable device comprising a tubular graft with a stent over the graft and an outer layer of PTFE wound about the stent, col. 20, lines 1-11. Banas also discloses that self-expanding stents can be incorporated in the stent-graft and made from shape memory material, such as Nitinol, col. 12, lines 60-64. Banas additionally discloses that balloon expandable stents can be employed with the graft, col. 13, lines 24-29. It can be construed that ptfe particles are deposited between the base graft and outer layer since aqueous PTFE can be used, which inherently has particles therein, col. 10, lines 1-5. Banas discloses the inner base graft and outer layer are bonded by heating, col. 9, lines

58-67. However, Banas does not disclose a stent having linear connectors with zigzag elements or that the longitudinal length of the stent remains constant with expansion. Frantzen teaches a stent (Fig. 10) with zigzag elements **20** with adjacent turns connected by a linear connector **90**. Frantzen also teaches that the stent length remains constant with expansion, col. 9, lines 35-39. It would have been obvious to one of ordinary skill in the art to use zigzag elements with a linear connector as taught by Frantzen in the graft of Banas et al. such that it provides a non-foreshortening stent for maximum vessel coverage.

Claims 114-116,118,121-128,130,133-137 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banas et al. (5749880) in view of Lau et al. (6066168). Banas is explained *supra*. However, Banas does not disclose a stent having linear connectors with sinusoidal elements or that the longitudinal length of the stent remains constant with expansion. Lau et al. teaches a stent (Fig. 11) with sinusoidal elements **12** with adjacent turns connected by a linear connector **13**. Lau also teaches that the length remains constant with expansion of the stent, col. 2, lines 44-46. It would have been obvious to one of ordinary skill in the art to use sinusoidal elements with a linear connector as taught by Lau et al. in the graft of Banas et al. such that it provides a non-foreshortening stent for maximum vessel coverage.

Claims 119,120,131,132 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banas et al. '880 in view of Frantzen '606 as applied to claims 114,126 above, and further in view of Myers et al. (5700285). Banas as modified by Frantzen is explained as before. Banas discloses at least one overlapping layer of tape,

col. 13, lines 61-65. However, Banas in view of Frantzen fail to disclose the tape has a thickness less than 0.015 inches. Myers discloses a thickness for the tape less than 0.015 inches, col. 8, lines 3,4. It would have been obvious to one of ordinary skill in the art to use a tape with a thickness less than 0.015 inches as taught by Myers et al. with the stent-graft of Banas as modified by Frantzen such that it has a low profile making insertion in a catheter or sheath easier.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian Pellegrino
TC 3700, AU 3738

